



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0157; FRL-9994-63]

Lactic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of lactic acid (CAS Reg. No. 50-21-5) when used as an inert ingredient (acidifier) on food-contact surfaces in public eating places, dairy processing equipment, food-processing equipment and utensils at 10,000 parts per million (ppm). Ecolab Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of lactic acid when used in accordance with the terms specified in the regulation.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0157, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0157 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0157, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),

(28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of May 18, 2018 (83 FR 23247) (FRL-9976-87), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11113) by Ecolab Inc., 655 Lone Oak Drive, Eagan, MN 55121. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of lactic acid (CAS Reg. No. 50-21-5) when used as an inert ingredient (acidifier) in pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, food-processing equipment and utensils at 10,000 parts per million (ppm). That document referenced a summary of the petition prepared by Ecolab Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term

“inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA, in determining whether an exemption would be safe, to take into account the considerations set forth in subparagraphs (b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a

result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for lactic acid including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with lactic acid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by lactic acid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Lactic acid is practically non-toxic to mammals, apart from irritation stemming from its low pH. It is an endogenous compound produced in the mammalian system. L-lactic acid (lactate) is a product of fermentation in the muscles produced from pyruvate via lactate dehydrogenase. Lactate is also generated from glucose under aerobic conditions in some tissues and cell types. L-Lactic acid is normally found in the blood and interstitial fluid of humans at a

level of 10 mg/dL (EPA 2009). In addition, L-lactic acid occurs naturally in several foods, primarily found in fermented milk products such as sour milk, cheese, buttermilk and yogurt. It also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil.

The available acute toxicity studies indicate that lactic acid is not acutely toxic via the oral or inhalation route of exposure. Because the test substance (80% lactic acid) has a very low pH (<1), L-lactic acid is a severe dermal irritant in rabbits but not a skin sensitizer at high concentrations (e.g., 80%).

Although some minor effects were observed in repeat dosing studies in rats (e.g., decrease in body weight gain or organ weight gain), no significant systemic toxicity was identified for lactic acid, even at dose levels greater than 1,000 mg/kg/day. In addition, there was no indication of developmental toxicity in a developmental toxicity study in mice. Furthermore, none of the available data indicate that lactic acid is neurotoxic, immunotoxic, or carcinogenic.

Based on a review of 15 mutagenicity and clastogenicity studies on lactic acid and the ammonium, calcium, and sodium salts of lactic acid, EPA notes that the results were negative for all studies and there is no evidence that lactic acid is genotoxic.

In an *in vitro* chromosomal aberration study, some pseudo-positive reactions were observed at low pH.

B. Toxicological Points of Departure/Levels of Concern

Although the toxicity database for lactic acid is limited, the toxicity profile indicates no significant systemic toxicity even at high dose levels. Since no toxicity is observed, an endpoint of concern for risk assessment purposes was not identified.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to lactic acid, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from lactic acid in food as follows:

Dietary exposure to lactic acid may occur following ingestion of foods containing residues of lactic acid from its use as an acidifier in pesticide formulations applied to food-contact surfaces as well as from other pesticidal uses that are already approved that may result in residues on treated crops. In addition, lactic acid occurs naturally in several foods and in the soil. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Lactic acid may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the lack of a hazard endpoint of concern above, a quantitative residential exposure assessment for lactic acid was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found lactic acid to share a common mechanism of toxicity with any other substances, and lactic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that lactic acid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of lactic acid. That qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of lactic acid, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of lactic acid will not pose a risk to the U.S. population, including infants and children, and that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to lactic acid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for lactic acid (CAS Reg. No. 50-21-5) when used as an inert ingredient (acidifier) in pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, food-processing equipment and utensils at 10,000 ppm.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule

in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 5, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.940, add alphabetically the inert ingredient “lactic acid” to the table in paragraph (a) and remove the inert ingredient “lactic acid” from the table in paragraph (c).

The addition reads as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * *		
Lactic acid	50-21-5	When ready for use, the end-use concentration is not to exceed 10,000 ppm in antimicrobial formulations applied to food-contact surfaces in public eating places
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[FR Doc. 2019-15647 Filed: 7/25/2019 8:45 am; Publication Date: 7/26/2019]